K062213

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BIOPLEX 2200 EBV IgM KIT, CALIBRATORS, AND CONTROLS 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number	510(k) Summary Report Date
k062213	December 7, 2006

MANUFACTURER INFORMATION

Manufacturer	
Manufacturer Address	Bio-Rad Laboratories, Inc. Clinical Systems Division 4000 Alfred Nobel Drive Hercules, CA 94547
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Establishment Registration No.	2915274
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CLASSIFICATION INFORMATION

Classification Name	Epstein Barr Virus, Other (LSE)
Common Name:	Multi-Analyte Detection System EBV IgM
Product Trade Name	BioPlex 2200 EBV IgM on the BioPlex 2200 Multi-Analyte Detection System BioPlex 2200 EBV IgG Control Set BioPlex 2200 EBV IgG Calibrator Set
Device Class	Class I
Classification Panel	Microbiology
Regulation Number	866.3235

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LEGALLY MARKETED EQUIVALENT (SE) DEVICES

	BioPlex2200 EBV IgG Analyte	Comparative FDA Cleared PREDICATE DEVICE	510(k) Number	Decision Date
1.	EBV VCA	Diasorin EBV VCA IgM Capture EIA	946157	6/7/95
2.	Heterophile	Wampole Monolatex	862008	7/03/86

DEVICE DESCRIPTION

The BioPlex 2200 EBV IgM kit uses multiplex flow immunoassay, a methodology that greatly resembles traditional EIA, but permits simultaneous detection and identification of many antibodies in a single tube. Two (2) different populations of dyed beads are coated with proteins associated with infectious mononucleosis. One (1) is coated with an *E. coli* derived recombinant fusion protein, EBV VCA p18 (40kD), and the other is coated with horse erythrocyte stromal extract (heterophile antigen). The BioPlex 2200 System combines an aliquot of patient sample, sample diluent containing goat anti-human IgG, and bead reagent into a reaction vessel. The mixture is incubated at 37°C. After a wash cycle, anti-human IgM antibody, conjugated to phycoerythrin (PE), is added to the dyed beads and this mixture is incubated at 37°C. The excess conjugate is removed in another wash cycle, and the beads are re-suspended in wash buffer. The bead mixture then passes through the detector. The identity of the dyed beads is determined by the fluorescence of the dyes, and the amount of antibody captured by the antigen is determined by the fluorescence of the attached PE.

Three additional dyed beads, an Internal Standard Bead (ISB), a Serum Verification Bead (SVB), and a Reagent Blank Bead (RBB), are present in each reaction mixture to verify detector response, the addition of serum or plasma to the reaction vessel, and the absence of significant non-specific binding in serum or plasma respectively. The instrument is calibrated using a set of two (2) distinct calibrator vials, supplied separately by Bio-Rad Laboratories. A combination of two (2) vials representing two (2) different antibody concentrations is used for calibration. The result for each of these antibodies is expressed as an antibody index (AI).

KIT COMPONENTS

EBV IgM Reagent Pack (Catalog No. 665-1350). The reagent pack contains supplies sufficient for 100 tests.

Vial	Description
Bead Set	One (1) 10 mL vial, containing 2 different populations of dyed beads coated with affinity-purified *E. coli* derived recombinant protein to EBV VCA p18 (40kD), and Heterophile antigen (horse erythrocyte stromal extract); an Internal Standard (ISB), a Serum Verification (SVB), and a Reagent Blank (RBB); with Glycerol and protein stabilizers (bovine) in a MOPS (3-[N-Morpholino] propanesulfonic acid) buffer. ProClin® 300 (0.3%) and sodium azide (<0.1%) as preservatives.
Conjugate	One (1) 5 mL vial, containing donkey anti-human IgM/phycoerythrin conjugate and murine monoclonal anti-human FXIII / phycoerythrin conjugate, in a phosphate buffer. Proclin® 300 (0.3%) and Sodium azide (0.1%) as preservatives.
Sample Diluent	One (1) 10 mL vial, containing goat anti-human IgG and protein stabilizers (bovine and murine) in a triethanolamine buffer. Proclin® 300 (0.3%) and Sodium azide (0.1%) as preservatives.

ADDITIONAL REQUIRED ITEMS, AVAILABLE FROM BIO-RAD

Catalog #	Description
663-1300	BioPlex 2200 EBV IgM Calibrator Set: Two (2) 500 µL vials, containing EBV VCA and heterophile antibodies, in a human serum matrix made from defibrinated plasma. ProClin® 300 (0.3%) as a preservative for all calibrators.
663-1330	BioPlex 2200 EBV IgM Control Set: Two (2) 1.5 mL vials of Positive Control containing EBV VCA and heterophile antibodies, in a human serum matrix made from defibrinated plasma; and two (2) 1.5 mL vials of Negative Control in a human serum matrix made from defibrinated plasma. ProClin® 300 (0.3%) as a preservative for all controls.
660-0817	BioPlex 2200 System Sheath Fluid: Two (2) 4 L bottles containing Phosphate Buffered Saline (PBS). Proclin® 300 (0.3%) and Sodium azide (0.1%) as preservatives.
660-0818	BioPlex 2200 System Wash Solution: One (1) 10 L bottle containing Phosphate Buffered Saline (PBS) and Tween 20. Proclin® 300 (0.3%) and Sodium azide (0.1%) as preservatives.
660-0000	BioPlex 2200 Instrument and Software.

INTENDED USE / INDICATIONS FOR USE

The BioPlex 2200 EBV IgM kit is a multiplex flow immunoassay intended for the qualitative detection of two (2) separate analytes; Epstein-Barr Virus Viral Capsid Antigen (EBV VCA) IgM antibodies and Heterophile antibodies in human serum. The test system can be used in conjunction with the BioPlex 2200 EBV IgG kit as an aid in the laboratory diagnosis of infectious mononucleosis (IM).

The EBV IgM kit is intended for use with the Bio-Rad BioPlex 2200 System.

Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients, cord blood, neonatal specimens, or infants. Assay performance characteristics have not been established for the diagnosis of nasopharyngeal carcinoma, Burkitt's lymphoma, and other EBV-associated lymphomas.

BioPlex 2200 EBV IgM Calibrator Set
The BioPlex 2200 EBV IgM Calibrator Set is intended for the calibration of the BioPlex 2200 EBV IgM Reagent Pack.

BioPlex 2200 EBV IgM Control Set
The BioPlex 2200 EBV IgM Control Set is intended for use as an assayed quality control to monitor the overall performance of the BioPlex 2200 Instrument and BioPlex 2200 EBV IgM Reagent Pack in the clinical laboratory. The performance of the BioPlex 2200 EBV IgM Control Set has not been established with any other EBV assays.

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TECHNOLOGICAL CHARACTERISTICS

The following tables summarize similarities and differences between the BioPlex 2200 EBV IgG Kit, Calibrators, and Controls and the predicate devices used in comparative studies with the BioPlex 2200 EBV IgG Kit.

A. BioPlex 2200 EBV IgM Assay: EBV VCA

Table 1: Similarities between reagents and materials

Similarities between Components / Materials	**BioPlex 2200 EBV IgM Kit**	**Predicate EBV VCA IgM Reverse Capture EIA**
Reagents	Wash Buffer, Sample Diluent	Wash Buffer, Sample Diluent
Calibrator(s)	Calibrators	Calibrators
Controls	Negative Control and Multi-Analyte Positive Control (EBV VCA, EBV NA-1, and EBV EA-D)	Negative Control, Low Positive Control, and High Positive Control

Table 2: Similarities between reagents with regard to function and use

Similarities between Function and Use	**BioPlex 2200 EBV IgM Kit**	**Predicate EBV VCA IgM Reverse Capture EIA**
Intended Use	Qualitative detection of IgM antibodies in human serum to EBV Viral Capsid Antigen (VCA).	Qualitative determination of IgM antibodies in human serum to EBV Viral Capsid Antigen (VCA).
Matrices	Serum	Serum

Table 3: Differences between reagents and materials

Differences between Components / Materials	**BioPlex 2200 EBV IgM Kit**	**Predicate EBV VCA IgM Reverse Capture EIA**
Solid Phase	Bead reagent - dyed antigen coated beads	96 well microplate – antigen coated microwells
Reagents	Conjugate (Anti-human IgM / Phycoerythrin)	Enzyme Tracer (Rat monoclonal anti-p18 conjugated with horse-radish peroxidase), Tracer Diluent, Reconstitution Solution, Chromogen / Substrate (TMB), Stop Solution
Sheath Fluid	Sheath Fluid is used to suspend the bead reagent and introduce it into the detector.	Not similar; not utilized in EIA's.

Table 4: Differences between reagents with regard to function and use

Differences between Function and Use	BioPlex 2200 EBV IgM Kit	Predicate EBV VCA IgM Reverse Capture EIA
Intended Use	Qualitative detection of IgM antibodies in human serum to EBV Viral Capsid Antigen (VCA).	Semi-quantitative detection of IgM antibodies in human serum to EBV Viral Capsid Antigen (VCA).
Analyte Detection	Multi-Analyte Detection (human IgG antibodies to EBV VCA, EBV NA-1, and EBV EA-D)	Single Analyte Detection (human IgM antibody to EBV Viral Capsid Antigen)

B. BioPlex 2200 EBV IgM Assay: Heterophile

Table 5: Similarities between reagents and materials

Similarities between Components / Materials	BioPlex 2200 EBV IgM Kit	Predicate MONO-LATEX Latex Agglutination Test
Controls	Negative Control and Multi-Analyte Positive Control (EBV VCA IgM and Heterophile)	Negative Control and Positive Control

Table 6: Similarities between reagents with regard to function and use

Similarities between Components / Materials	BioPlex 2200 EBV IgM Kit	Predicate MONO-LATEX Latex Agglutination Test
Intended Use	Qualitative detection of heterophile antibodies	Qualitative detection of heterophile antibodies
Matrices	Serum	Serum

Table 7: Differences between reagents and materials

Differences between Components / Materials	BioPlex 2200 EBV IgM Kit	Predicate MONO-LATEX Latex Agglutination Test
Solid Phase	Bead reagent - dyed antigen coated beads	Latex reagent – suspension of mononucleosis antigen sensitized latex particles
Reagents	Sample Diluent, Conjugate, Wash Buffer, Sheath Fluid	Not similar; these reagents not utilized in latex agglutination tests.
Calibrators	Calibrators	Not similar; not utilized in latex agglutination tests.

Table 8: Differences between reagents with regard to function and use

Differences between Components / Materials	**BioPlex 2200 EBV IgM Kit**	**Predicate MONO-LATEX Latex Agglutination Test**
Intended Use	Qualitative detection of heterophile antibodies.	Semi-quantitative detection of heterophile antibodies.
Matrices	Serum	Plasma
Analyte Detection	Multi-Analyte Detection (human EBV VCA IgM and heterophile antibodies)	Single Analyte Detection (human heterophile antibodies)

PERFORMANCE SUMMARY

A. Expected Values

Expected values for the EBV IgM kit are presented by age and gender in the following tables for serum samples from unselected hospitalized pediatric and adult patients (N=302) and patients for which an EBV test was ordered (N=619). A total of 303 serum samples from unselected hospitalized pediatric and adult patients and a total of 621 serum samples from patients for which an EBV test was ordered were tested. One (1) sample from the unselected hospitalized population, and two (2) samples from the patients for which an EBV test was ordered population were excluded due to RBB analysis error messages during BioPlex 2200 EBV IgM testing. For all analytes, results of ≤0.8 AI are negative, 0.9 and 1.0 AI are equivocal, and ≥1.1 AI are reported as positive.

Table 9: Hospitalized Patient Samples: EBV VCA IgM

Age	Gender	BioPlex 2200 EBV VCA IgM						Total
		Positive		Equivocal		Negative		
		N	%	N	%	N	%	N
< 5 years of age	F	3	11%	0	0%	24	89%	27
	M	1	5%	0	0%	19	95%	20
5-12 years of age	F	2	9%	0	0%	20	91%	22
	M	1	3%	1	3%	32	94%	34
13-20 years of age	F	5	14%	1	3%	29	83%	35
	M	0	0%	1	7%	14	93%	15
21-30 years of age	F	0	0%	0	0%	6	100%	6
	M	0	0%	0	0%	2	100%	2
31-40 years of age	F	0	0%	0	0%	10	100%	10
	M	0	0%	0	0%	11	100%	11
41-50 years of age	F	1	8%	0	0%	12	92%	13
	M	1	14%	0	0%	6	86%	7
51-60 years of age	F	0	0%	0	0%	23	100%	23
	M	0	0%	1	5%	18	95%	19
61-70 years of age	F	0	0%	0	0%	11	100%	11
	M	0	0%	0	0%	11	100%	11
71-80 years of age	F	1	9%	0	0%	10	91%	11
	M	0	0%	0	0%	6	100%	6
81-90 years of age	F	0	0%	0	0%	11	100%	11
	M	0	0%	0	0%	6	100%	6
91-100 years of age	F	0	0%	0	0%	0	0%	0
	M	0	0%	0	0%	2	100%	2
Total		15	5%	4	1%	283	94%	302

Table 10: Hospitalized Patient Samples: Heterophile

Age	Gender	BioPlex 2200 Heterophile						Total
		Positive		Equivocal		Negative		
		N	%	N	%	N	%	N
< 5 years of age	F	1	4%	0	0%	26	96%	27
	M	0	0%	0	0%	20	100%	20
5-12 years of age	F	0	0%	0	0%	22	100%	22
	M	1	3%	0	0%	33	97%	34
13-20 years of age	F	0	0%	0	0%	35	100%	35
	M	0	0%	0	0%	15	100%	15
21-30 years of age	F	0	0%	0	0%	6	100%	6
	M	0	0%	0	0%	2	100%	2
31-40 years of age	F	0	0%	0	0%	10	100%	10
	M	0	0%	0	0%	11	100%	11
41-50 years of age	F	0	0%	0	0%	13	100%	13
	M	0	0%	0	0%	7	100%	7
51-60 years of age	F	0	0%	0	0%	23	100%	23
	M	0	0%	0	0%	19	100%	19
61-70 years of age	F	0	0%	0	0%	11	100%	11
	M	0	0%	0	0%	11	100%	11
71-80 years of age	F	0	0%	0	0%	11	100%	11
	M	0	0%	0	0%	6	100%	6
81-90 years of age	F	0	0%	0	0%	11	100%	11
	M	0	0%	0	0%	6	100%	6
91-100 years of age	F	0	0%	0	0%	0	0%	0
	M	0	0%	0	0%	2	100%	2
Total		2	1%	0	0%	300	99%	302

Table 11: Samples from Patients for which an EBV Test was Ordered: EBV VCA IgM

Age	Gender	BioPlex 2200 EBV VCA IgM						Total
		Positive		Equivocal		Negative		
		N	%	N	%	N	%	N
< 5 years of age	F	3	10%	0	0%	27	90%	30
	M	6	18%	0	0%	27	82%	33
5-12 years of age	F	9	15%	1	2%	52	84%	62
	M	6	10%	1	2%	55	89%	62
13-20 years of age	F	17	22%	2	3%	59	76%	78
	M	10	26%	1	3%	27	71%	38
21-30 years of age	F	5	11%	1	2%	40	87%	46
	M	7	21%	1	3%	25	76%	33
31-40 years of age	F	5	10%	1	2%	46	88%	52
	M	1	4%	0	0%	23	96%	24
41-50 years of age	F	3	9%	1	3%	30	88%	34
	M	4	13%	1	3%	26	84%	31
51-60 years of age	F	4	15%	1	4%	22	81%	27
	M	2	8%	1	4%	23	88%	26
61-70 years of age	F	1	8%	0	0%	12	92%	13
	M	0	0%	0	0%	21	100%	21
71-80 years of age	F	0	0%	0	0%	2	100%	2
	M	0	0%	0	0%	3	100%	3
81-90 years of age	F	0	0%	0	0%	2	100%	2
	M	0	0%	0	0%	2	100%	2
91-100 years of age	F	0	0%	0	0%	0	0%	0
	M	0	0%	0	0%	0	0%	0
Total		83	13%	12	2%	524	85%	619

Table 12: Samples from Patients for which an EBV Test was Ordered: Heterophile

Age	Gender	BioPlex 2200 Heterophile						Total
		Positive		Equivocal		Negative		
		N	%	N	%	N	%	N
< 5 years of age	F	0	0%	0	0%	30	100%	30
	M	0	0%	0	0%	33	100%	33
5-12 years of age	F	3	5%	0	0%	59	95%	62
	M	3	5%	0	0%	59	95%	62
13-20 years of age	F	8	10%	1	1%	69	88%	78
	M	7	18%	1	3%	30	79%	38
21-30 years of age	F	0	0%	2	4%	44	96%	46
	M	4	12%	0	0%	29	88%	33
31-40 years of age	F	0	0%	0	0%	52	100%	52
	M	1	4%	1	4%	22	92%	24
41-50 years of age	F	0	0%	0	0%	34	100%	34
	M	0	0%	0	0%	31	100%	31
51-60 years of age	F	0	0%	0	0%	27	100%	27
	M	0	0%	0	0%	26	100%	26
61-70 years of age	F	0	0%	0	0%	13	100%	13
	M	0	0%	0	0%	21	100%	21
71-80 years of age	F	0	0%	0	0%	2	100%	2
	M	0	0%	0	0%	3	100%	3
81-90 years of age	F	0	0%	0	0%	2	100%	2
	M	0	0%	0	0%	2	100%	2
91-100 years of age	F	0	0%	0	0%	0	0%	0
	M	0	0%	0	0%	0	0%	0
Total		26	4%	5	1%	588	95%	619

The distribution of BioPlex 2200 EBV VCA IgM and Heterophile AI values for serum samples from adult and pediatric unselected hospitalized patients and from patients for which an EBV test was ordered are presented in the following histograms.

Figure 1: Hospitalized Patient Samples: EBV VCA IgM

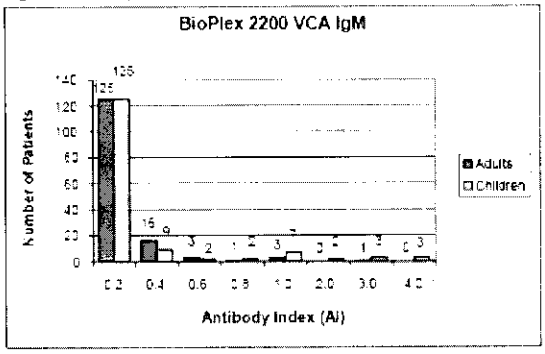


Figure 2: Hospitalized Patient Samples: Heterophile

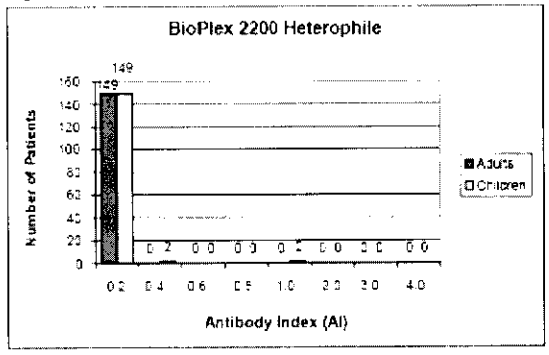


Figure 3. Samples from Patients for which an EBV Test was Ordered: EBV VCA IgM

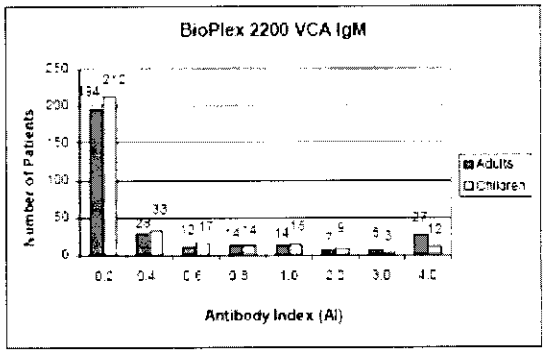
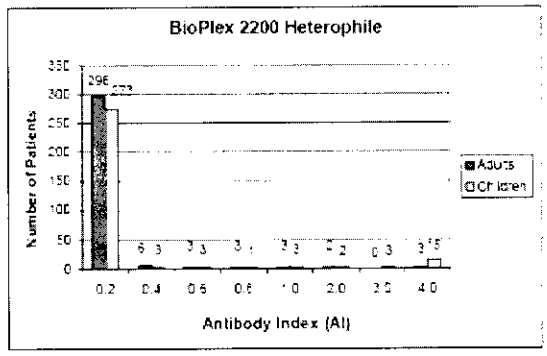


Figure 4. Samples from Patients for which an EBV Test was Ordered: Heterophile



B. Reproducibility Studies

A reproducibility panel, consisting of six (6) panel members was prepared by Bio-Rad Laboratories. Two (2) of the six (6) panel members had high levels of the antibodies contained in the BioPlex 2200 EBV IgM kit (EBV VCA IgM and Heterophile) and two (2) of the six (6) panel members had antibody levels near the cutoff, both prepared from positive patient samples. Two (2) of the six (6) panel members were negative (one high negative and one low negative) for both of the analytes. In addition, a positive control (antibody positive for both analytes) and a negative control (antibody negative for both analytes) were also tested. Reproducibility testing was performed at each of three (3) US testing facilities on a total of three (3) lots of the EBV IgM kit, three (3) lots of the EBV IgM Calibrator Set and three (3) lots of the EBV IgM Control Set. The panels were provided to each of the testing sites. Each of the six (6) panel members and positive and negative controls was tested in quadruple (x4) on each day for three (3) days at each of three (3) US testing facilities using one (1) lot of EBV IgM kit, one (1) lot of EBV IgM Calibrator Set and one (1) lot of EBV IgM Control Set (4 times x 3 days x 3 sites = 36 replicates per panel member and controls). The data were analyzed for intra-assay and inter-assay reproducibility according to the principles described in the Clinical Laboratory Standards Institute guidance EP5-A2, revised November 2004 and ISO/TR 22971:2205. The standard deviation (SD) and percent coefficient of variation (%CV) were calculated. Positive results can be found in Tables 12 and 13.

Table 12: Reproducibility Results; BioPlex 2200 EBV VCA IgM

EBV VCA IgM Panel Members	Sample N	Grand Mean AI	Within-Run		Between-Day		Between-Run		Between-Site*		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
High Positive 1	36	1.9	0.1	5.9%	0.1	4.5%	0.1	3.8%	0.0	0.0%	0.2	8.4%
High Positive 2	36	2.0	0.1	3.5%	0.0	0.0%	0.1	5.8%	0.0	2.2%	0.1	7.1%
Low Positive 1	35**	1.2	0.1	4.4%	0.1	5.6%	0.0	1.4%	0.0	3.9%	0.1	8.3%
Low Positive 2	36	1.4	0.1	5.8%	0.1	4.8%	0.0	0.0%	0.0	2.4%	0.1	7.9%
Positive Control	36	2.0	0.1	5.5%	0.1	2.8%	0.1	3.0%	0.3	15.9%	0.3	17.2%

**Between site variance includes between lot variance.*
***1 replicate missing due to insufficient sample volume.*

Table 13: Reproducibility Results; BioPlex 2200 Heterophile

Heterophile Panel Members	Sample N	Grand Mean AI	Within-Run		Between-Day		Between-Run		Between-Site*		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
High Positive 1	36	2.8	0.1	2.8%	0.0	0.0%	0.1	5.2%	0.1	5.1%	0.2	7.8%
High Positive 2	36	2.7	0.1	3.2%	0.0	0.0%	0.1	4.4%	0.0	0.7%	0.1	5.5%
Low Positive 1	35**	1.9	0.1	5.0%	0.0	0.0%	0.0	0.0%	0.0	2.3%	0.1	5.5%
Low Positive 2	36	1.8	0.1	4.7%	0.0	1.0%	0.0	0.0%	0.1	5.6%	0.1	7.4%
Positive Control	36	2.5	0.1	5.3%	0.1	2.6%	0.0	0.0%	0.0	0.0%	0.1	5.9%

**Between site variance includes between lot variance.*
***1 replicate missing due to insufficient sample volume.*

C. Precision Studies

A precision panel, consisting of six (6) panel members was prepared by Bio-Rad Laboratories. Two (2) of the six (6) panel members had high levels of the antibodies contained in the BioPlex 2200 EBV IgG kit EBV IgM kit (EBV VCA IgM and Heterophile) and two (2) of the six (6) panel members had antibody levels near the cutoff, both prepared from positive patient samples. Two (2) of the six (6) panel members were negative (one high negative and one low negative) for both of the analytes.

Precision testing was performed at Bio-Rad Laboratories on one lot of the EBV IgM kit, one lot of the EBV IgM Calibrator Set and one lot of the EBV IgM Control Set. Each of the six (6) panel members was tested in duplicate (x2) on two (2) runs per day for ten (10) days using one (1) lot of EBV IgM kit, one (1) lot of EBV IgM Calibrator Set and one (1) lot of EBV IgM Control Set (2 times x 2 runs x 10 days = 40 replicates per panel member). The data were analyzed for intra-assay and inter-assay precision according to the principles described in the Clinical Laboratory Standards Institute guidance EP5-A2, revised November 2004 and ISO/TR 22971:2205. The standard deviation (SD) and percent coefficient of variation (%CV) were calculated.

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Table 14: Precision Results; BioPlex 2200 EBV VCA IgM

EBV VCA IgM Panel Members	Sample N*	AI Mean	Within-Run		Between-Day		Between-Run		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
High Positive 1	42	2.5	0.2	8.8%	0.1	2.4%	0.2	6.6%	0.3	11.2%
High Positive 2	43	2.7	0.2	5.6%	0.2	6.9%	0.1	1.8%	0.2	9.1%
Low Positive 1	42	1.6	0.1	6.5%	0.0	0.0%	0.1	4.3%	0.1	7.8%
Low Positive 2	42	1.9	0.1	4.4%	0.1	2.9%	0.1	4.8%	0.1	7.1%
High Negative	43	0.7	0.0	6.4%	0.0	0.0%	0.0	2.7%	0.0	7.0%
Low Negative	43	0.1	0.0	0.0%	0.0	0.0%	0.0	0.0%	0.0	0.0%

Table 15: Precision Results; BioPlex 2200 Heterophile

Heterophile Panel Members	Sample N*	AI Mean	Within-Run		Between-Day		Between-Run		Total	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
High Positive 1	42	2.8	0.1	3.7%	0.2	8.6%	0.1	1.8%	0.3	9.5%
High Positive 2	43	2.8	0.1	4.7%	0.3	9.9%	0.1	5.3%	0.3	12.2%
Low Positive 1	42	2.1	0.1	3.9%	0.1	3.7%	0.2	9.0%	0.2	10.5%
Low Positive 2	42	1.9	0.1	3.9%	0.1	4.6%	0.1	7.5%	0.2	9.6%
High Negative	43	0.7	0.0	7.0%	0.0	4.6%	0.0	0.0%	0.1	8.4%
Low Negative	43	0.0	0.0	0.0%	0.0	0.0%	0.0	0.0%	0.0	0.0%

D. Comparative Testing

Typical Antibody Response Characterization

The following table demonstrates a generally accepted algorithm for classifying patients into an EBV status via serologic profiles. EBV status can be applied to any patient based on results of standard tests. In acute IM, both EBV IgM and EBV IgG antibodies to viral capsid antigen (VCA) rise rapidly. EBV VCA IgM antibody disappears over about four weeks. Heterophile antibody, which is of the IgM class, appears only during acute infection and fades rapidly over about four weeks. EBV EA-D IgG antibody shows a transient raise during acute infection, undetectable after 3 - 6 months. EBV NA-1 IgG antibody usually appears 3 months after initial infection and remains for life.

Table 16: Serological Status

EBV Serological Status	EBV NA-1 IgG	EBV VCA IgG	EBV EA-D IgG	EBV VCA IgM	Heterophile Antibody
Primary Acute	Neg (-)	Pos (+)	Pos (+)	Pos (+)	Neg (-)
	Neg (-)	Neg (-)	Pos (+)	Pos (+)	Pos (+)
	Neg (-)	Pos (+)	Neg (-)	Pos (+)	Pos (+)
	Neg (-)	Neg (-)	Neg (-)	Pos (+)	Pos (+)
	Neg (-)	Neg (-)	Neg (-)	Pos (+)	Neg (-)
	Neg (-)	Neg (-)	Pos (+)	Pos (+)	Neg (-)
	Neg (-)	Pos (+)	Pos (+)	Pos (+)	Pos (+)
	Neg (-)	Pos (+)	Pos (+)	Neg (-)	Pos (+)
Late Acute	Neg (-)	Pos (+)	Neg (-)	Pos (+)	Neg (-)
	Pos (+)	Pos (+)	Pos (+)	Pos (+)	Pos (+)
	Pos (+)	Pos (+)	Pos (+)	Pos (+)	Neg (-)
	Pos (+)	Pos (+)	Neg (-)	Pos (+)	Pos (+)
	Pos (+)	Pos (+)	Pos (+)	Neg (-)	Neg (-)
	Pos (+)	Pos (+)	Neg (-)	Pos (+)	Neg (-)
Recovering	Neg (-)	Pos (+)	Pos (+)	Neg (-)	Neg (-)
Previous Infection	Neg (-)	Pos (+)	Neg (-)	Neg (-)	Neg (-)
	Pos (+)	Pos (+)	Neg (-)	Neg (-)	Neg (-)
Susceptible	Neg (-)	Neg (-)	Neg (-)	Neg (-)	Neg (-)

Notes: For the purposes of serological characterization, equivocal results were considered negative. Any serological pattern not identified in Table 16 should be considered inconclusive.

Comparison of BioPlex 2200 EBV IgM kit and Microplate EIA/Agglutination Tests

Performance of the EBV IgM kit was tested against corresponding commercially available microplate EIA/agglutination tests. A total of 621 banked serum samples from patients for which an EBV test was ordered were tested at 3 U.S. clinical testing sites. The EBV IgG kit was run in conjunction with the EBV IgM kit to allow for a complete antibody response profile. The characterization by antibody response was not compared with clinical data regarding presence, absence or status of disease. Two (2) samples were excluded due to RBB analysis error messages during BioPlex 2200 EBV IgM testing. One (1) sample was excluded due to RBB analysis error messages during BioPlex 2200 EBV IgG testing. Using Table 16 as a guideline, results were analyzed by BioPlex 2200 EBV IgM analytes and corresponding EBV IgM reference assays according to serological characterization based on reference assay results. For the purpose of percent agreement calculations, BioPlex 2200 EBV IgM equivocal results were assigned to the opposite clinical interpretation than that of the corresponding reference assay result. Results from all sites are shown and summarized in Tables 17 - 20.

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Table 17. BioPlex 2200 EBV VCA IgM vs. EIA: Comparison by Serological Pattern Characterization

EBV Serological Status	Reference EBV VCA IgM Interpretation						Total
	Positive			Negative			
	BioPlex 2200 EBV VCA IgM			BioPlex 2200 EBV VCA IgM			
	Pos	Eqv	Neg	Pos	Eqv	Neg	
	N	N	N	N	N	N	N
Primary Acute	30	1	0	0	0	0	31
Late Acute	31	1	16	1	4	57	110
Recovering	0	0	0	1	0	3	4
Previous Infection	0	0	0	6	6	293	305
Susceptible	0	0	0	4	0	123	127
Inconclusive	4	0	0	6	0	31	41
Overall	65	2	16	18	10	507	618

Table 18: BioPlex 2200 EBV VCA IgM vs. EIA: Percent Agreement & Confidence Intervals by Serological Pattern Characterization

EBV Serological Status	Positive Agreement		95% CI	Negative Agreement		95% CI
Primary Acute	(30/31)	96.8%	83.8 - 99.4%	(0/0)	N/A*	N/A*
Late Acute	(31/48)	64.6%	50.4 - 76.6%	(57/62)	91.9%	82.5 - 96.5%
Recovering	(0/0)	N/A*	N/A*	(3/4)	75.0%	30.1 - 95.4%
Previous Infection	(0/0)	N/A*	N/A*	(293/305)	96.1%	93.2 - 97.7%
Susceptible	(0/0)	N/A*	N/A*	(123/127)	96.9%	92.2 - 98.8%
Inconclusive	(4/4)	100%	51.0-100%	(31/37)	83.8%	68.9 - 92.3%
Overall	(65/83)	78.3%	68.3 - 85.8%	(507/535)	94.8%	92.5 - 96.4%

**In cases where agreement resulted in (0/0) samples, percent agreement and 95% confidence interval could not be calculated.*

Table 19: BioPlex 2200 Heterophile vs. Agglutination Test: Comparison by Serological Pattern Characterization

EBV Serological Status	Reference Heterophile Interpretation						Total
	Positive			Negative			
	BioPlex 2200 Heterophile			BioPlex 2200 Heterophile			
	Pos	Eqv	Neg	Pos	Eqv	Neg	
	N	N	N	N	N	N	N
Primary Acute	16	1	2	2	0	10	31
Late Acute	3	0	1	1	1	104	110
Recovering	0	0	0	0	0	4	4
Previous Infection	0	0	0	0	3	302	305
Susceptible	0	0	0	0	0	127	127
Inconclusive	4	0	23	0	0	14	41
Overall	23	1	26	3	4	561	618

Table 20: BioPlex 2200 Heterophile vs. Agglutination Test: Percent Agreement & Confidence Intervals by Serological Pattern Characterization

EBV Serological Status	Positive Agreement		95% CI	Negative Agreement		95% CI
Primary Acute	(16/19)	84.2%	62.4 - 94.5%	(10/12)	83.3%	55.2 - 95.3%
Late Acute	(3/4)	75.0%	30.1 - 95.4%	(104/106)	98.1%	93.4 - 99.5%
Recovering	(0/0)	N/A*	N/A*	(4/4)	100%	51.0 - 100%
Previous Infection	(0/0)	N/A*	N/A*	(302/305)	99.0%	97.1 - 99.7%
Susceptible	(0/0)	N/A*	N/A*	(127/127)	100%	97.1 - 100%
Inconclusive	(4/27)	14.8%	5.9 - 32.5%	(14/14)	100%	78.5 - 100%
Overall	(23/50)	46.0%	33.0 - 59.6%	(561/568)	98.8%	97.5 - 99.4%

**In cases where agreement resulted in (0/0) samples, percent agreement and 95% confidence interval could not be calculated.*

Comparison of BioPlex 2200 EBV IgM kit and Microplate EIA (known VCA IgM positive samples)
Performance of the EBV IgM kit was further tested with serum samples that were previously characterized as EBV VCA IgM positive samples by another commercially available IgM EIA. A total of 100 purchased EBV VCA IgM positive samples were tested with the EBV IgM kit against corresponding commercially available microplate EIA/agglutination tests at a U.S. clinical testing site. The EBV IgG kit was run in conjunction with the EBV IgM kit to allow for a complete antibody response profile. The characterization by antibody response was not compared with clinical data regarding presence, absence or status of disease. Using Table 16 as a guideline, results were analyzed by BioPlex 2200 EBV IgM analytes and corresponding EBV IgM reference assays according to serological characterization based on reference assay results. For the purpose of percent agreement calculations, BioPlex 2200 EBV IgM equivocal results were assigned to the opposite clinical interpretation than that of the corresponding reference assay result. Results are shown and summarized in Tables 21 - 25.

Table 21: BioPlex 2200 EBV VCA IgM vs. EIA: Comparison by Serological Pattern Characterization

EBV Serological Status	Reference EBV VCA IgM Interpretation						Total
	Positive			Negative			
	BioPlex 2200 EBV VCA IgM			BioPlex 2200 EBV VCA IgM			
	Pos	Eqv	Neg	Pos	Eqv	Neg	
	N	N	N	N	N	N	N
Late acute	100	0	0	0	0	0	100
Overall	100	0	0	0	0	0	100

Table 22: BioPlex 2200 EBV VCA IgM vs. EIA: Percent Agreement & Confidence Intervals by Serological Pattern Characterization

EBV Serological Status	Positive Agreement		95% CI	Negative Agreement		95% CI
Late acute	(100/100)	100%	96.3 - 100%	(0/0)	NA*	NA*
Overall	(100/100)	100%	96.3 - 100%	(0/0)	NA*	NA*

**In cases where agreement resulted in (0/0) samples, percent agreement and 95% confidence interval could not be calculated.*

Table 23: BioPlex 2200 Heterophile vs. Agglutination Test: Comparison by Serological Pattern Characterization

EBV Serological Status	Reference Heterophile Interpretation						Total
	Positive			Negative			
	BioPlex 2200 Heterophile			BioPlex 2200 Heterophile			
	Pos	Eqv	Neg	Pos	Eqv	Neg	
	N	N	N	N	N	N	N
Late acute	100	0	0	0	0	0	100
Overall	100	0	0	0	0	0	100

Table 24: BioPlex 2200 Heterophile vs. Agglutination Test: Percent Agreement & Confidence Intervals by Serological Pattern Characterization

EBV Serological Status	Positive Agreement		95% CI	Negative Agreement		95% CI
Late acute	(100/100)	100%	96.3 - 100%	(0/0)	NA*	NA*
Overall	(100/100)	100%	96.3 - 100%	(0/0)	NA*	NA*

**In cases where agreement resulted in (0/0) samples, percent agreement and 95% confidence interval could not be calculated.*

Comparison of EBV Serological Status

Using Table 16 as a guideline, samples characterized into serological status associated with EBV disease, using the commercially available microplate EIA and agglutination tests, were compared with characterizations using BioPlex 2200 EBV IgG and IgM kits. The BioPlex 2200 EBV IgM kit was run in conjunction with the BioPlex 2200 EBV IgG kit to allow for a complete antibody response profile. The characterization by antibody response was not compared with clinical data regarding presence, absence or status of disease. Results from 618 serum samples tested at 3 U.S. clinical testing sites are shown in Table 25.

Table 25: Comparison of EBV Serological Status

EBV Serological status		BioPlex 2200 EBV IgG & IgM Profile								
		Primary Acute	Late Acute	Recovering	Previous Infection	Susceptible	Inconclusive	Total	% Serological Agreement	95% Confidence Interval
Commercially Available Assays	Primary Acute	30	0	0	0	0	1	31	96.8%	83.8 - 99.4%
	Late Acute	5	90	1	13	0	1	110	81.8%	73.6 - 87.9%
	Recovering	1	0	3	0	0	0	4	75.0%	30.0 - 95.4%
	Previous Infection	0	31	2	263	4	5	305	86.2%	81.9 - 89.7%
	Susceptible	4	0	0	0	122	1	127	96.1%	91.1 - 98.3%
	Inconclusive	6	10	0	7	11	7	41	17.1%	8.5 - 31.3%
	Overall	46	131	6	283	137	15	618	83.3%	80.2 - 86.1%

Note: Calculations are performed for unshaded areas only.

Comparison of Acute and Non-acute EBV Serological Status

The results obtained from the summarized information provided in Table 26 were further classified into Acute Infection. Acute Infection includes Primary Acute and Late Acute. Non-Acute Infection includes Susceptible, Recovering and Previous Infection as defined in Table 16. Inconclusive includes any samples reactivity are not consistent with any category listed in Table 16. Results are summarized in Table 26.

Table 26: Acute vs. Non-acute

EBV Serological status		BioPlex 2200 EBV IgG & IgM Profile					
		Acute	Non-Acute	Inconclusive	Total	% Serological Agreement	95% Confidence Interval
Commercially Available Assays	Acute	125	14	2	141	88.7%	82.4 - 92.9%
	Non-Acute	36	394	6	436	90.4%	87.2 - 92.8%
	Inconclusive	16	18	7	41	17.1%	8.5 - 31.3%
	Overall	177	426	15	618	85.1%	82.1 – 87.7%

Note: Calculations are performed for unshaded areas only.

Comparison of EBV Serological Status (known IgM positive samples)
Using Table 16 as a guideline, samples characterized into serological status associated with EBV disease, using the commercially available microplate EIA and agglutination tests, were compared with characterizations using BioPlex 2200 EBV IgG and IgM kits. The BioPlex 2200 EBV IgM kit was run in conjunction with the BioPlex 2200 EBV IgG kit to allow for a complete antibody response profile. The characterization by antibody response was not compared with clinical data regarding presence, absence or status of disease. A total of 100 purchased EBV VCA IgM positive samples were tested at a U.S. clinical testing site. Results are shown in Table 27.

Table 27: Comparison of EBV Serological Status (known VCA IgM positive samples)

EBV Serological status		BioPlex 2200 EBV IgG & IgM Profile								
		Primary Acute	Late Acute	Recovering	Previous infection	Susceptible	Inconclusive	Total	% Serological Agreement	95% Confidence Interval
Commercially Available Assays	Primary Acute	0	0	0	0	0	0	0	N/A	N/A
	Late Acute	0	100	0	0	0	0	100	100%	96.3-100%
	Recovering	0	0	0	0	0	0	0	N/A	N/A
	Previous Infection	0	0	0	0	0	0	0	N/A	N/A
	Susceptible	0	0	0	0	0	0	0	N/A	N/A
	Inconclusive	0	0	0	0	0	0	0	N/A	N/A
	Overall	0	100	0	0	0	0	100	100%	96.3-100%

Note: Calculations are performed for unshaded areas only.

Comparison of Acute and Non-acute EBV Serological Status (known VCA IgM positive samples)
The results obtained from the summarized information provided in Table 27 were further classified into two groups; Acute Infection and Non-Acute Infection. Acute Infection includes Primary Acute and Late Acute. Non-Acute Infection includes samples characterized as Susceptible, Recovering and Previous Infection as defined in Table 16. Inconclusive includes any samples whose patterns of antibody reactivity are not consistent with any category listed in Table 16. Results are summarized in Table 28.

Table 28: Acute vs. Non-acute (known VCA IgM positive samples)

EBV Serological status		BioPlex 2200 EBV IgG & IgM Profile					
		Acute	Non-Acute	Inconclusive	Total	% Serological Agreement	95% Confidence Interval
Commercially Available Assays	Acute	100	0	0	100	100%	96.3-100%
	Non-Acute	0	0	0	0	N/A	N/A
	Inconclusive	0	0	0	0	N/A	N/A
	Overall	100	0	0	100	100%	96.3-100%

Note: Calculations are performed for unshaded areas only.

Primary Acute Serological Status by Age

The results from Table 28 with a Primary Acute serological status were further analyzed by age group. Results are summarized in Table 29.

Table 29: Primary Acute Serological Status by Age

EBV Primary Acute Infection Grouped by Age	N	BioPlex 2200 EBV VCA IgM			BioPlex 2200 Heterophile		
		Pos (+)	(%)	95% CI	Pos (+)	(%)	95% CI
< 5 Yrs	4	4	100%	51.0 - 100 %	0	0%	N/A
5 - 12 Yrs	7	7	100%	64.6 - 100 %	5*	71%	35.9 - 91.8%
13 - 20 Yrs	14	13	93%	68.5 - 98.7%	10	71%	45.4 - 88.3%
Adult ≥ 21 Yrs	6	6	100%	61.0 - 100%	3**	50%	18.8 - 81.2%
Total	31	30	97%	83.8 - 99.4%	18	58%	40.8 - 73.6%

**Two (2) samples were BioPlex 2200 positive, commercially available Heterophile Agglutination negative.*
***One (1) sample was commercially available Heterophile Agglutination positive, BioPlex 2200 negative.*

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D. Cross-Reactivity

A cross-reactivity study was performed to determine if samples from various disease states and other potentially interfering factors interfere with test results when tested with the BioPlex 2200 EBV IgM kit. A panel of at least ten (10) specimens* positive for each cross reactant were evaluated for possible cross reactivity with the BioPlex 2200 EBV IgM kit for both EBV IgM antibody assays. The test specimens were also evaluated on corresponding commercially available microplate EIA and latex agglutination tests. Due to the number of VCA IgM positive results obtained with the initial 10 Toxoplasmosis and CMV samples, an additional 33 toxoplasmosis and 42 CMV positive samples were tested with the BioPlex 2200 EBV IgM kit. This study was performed to demonstrate that the BioPlex 2200 VCA IgM assay does not exhibit cross reactivity with Toxoplasmosis or CMV IgM samples. For these additional samples, only those that exhibited positive reactivity were tested on corresponding commercially available microplate EIA and latex agglutination tests. Most of the samples evaluated were high positive for each disease state. The majority of all samples that elicited a positive result were also confirmed positive by the corresponding commercially available test, indicating reactivity to EBV IgM antibodies rather than cross reactivity with a potentially interfering factor. Results can be found in Table 30.

**Due to limited availability of samples, only four E. coli specimens were evaluated.*

Table 30: Cross-Reactivity

Cross Reactives	N	Method	BioPlex 2200 EBV IgM	
			EBV VCA	Heterophile
ANA	10	BioPlex 2200	1	0
		Commercial Assay	1	0
		Discrepants	0	0
Rubella IgM	10	BioPlex 2200	0	0
		Commercial Assay	0	0
		Discrepants	0	0
HSV IgM	10	BioPlex 2200	0	0
		Commercial Assay	0	0
		Discrepants	0	0
E. Coli	4*	BioPlex 2200	0	0
		Commercial Assay	N/A	N/A
		Discrepants	N/A	N/A
Toxo IgM		BioPlex 2200 (N)	43	43
		BioPlex 2200 (+)	14	0
		Commercial Assay (N)	14†	10††
		Commercial Assay (+)	9	0
		Discrepants	5	0
Rheumatoid Factor	10	BioPlex 2200	0	0
		Commercial Assay	0	0
		Discrepants	0	0
VZV IgM	10	BioPlex 2200	0	0
		Commercial Assay	0	0
		Discrepants	0	0
HIV	10*	BioPlex 2200	0	0
		Commercial Assay	N/A	N/A
		Discrepants	N/A	N/A
Pregnant women	10	BioPlex 2200	0	0
		Commercial Assay	0	0
		Discrepants	0	0
CMV IgM		BioPlex 2200 (N)	52	52
		BioPlex 2200 (+)	25	1
		Commercial Assay (N)	25†	10††
		Commercial Assay (+)	22	0
		Discrepants	3	1

**Commercially available assay data was not obtained, due to low sample volume.*
†Commercially available assay testing was performed on BioPlex 2200 positive samples only.
††Commercially available assay testing was performed on the initial ten samples evaluated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. David Bhend
Regulatory Affairs Associate
Bio-Rad Laboratories, Inc.
Diagnostics Group
6565 185th Ave, N.E.
Redmond, WA 98052

DEC - 8 2006

Re: k062213
Trade/Device Name: BioPlex 2200 EBV IgM Panel on the BioPlex 2200 Multi-Analyte Detection System
BioPlex 2200 EBV IgM Control Set
BioPlex 2200 EBV IgM Calibrator Set
Regulation Number: 21 CFR 866.5640
Regulation Name: Infectious mononucleosis immunological test system.
Regulatory Class: Class II
Product Code: LSE, KTN
Dated: November 13, 2006
Received: November 14, 2006

Dear Mr. Bhend:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

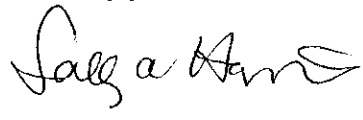
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: k062213

Device Name: BioPlex 2200 EBV IgM Kit on the BioPlex 2200 Multi-Analyte Detection System
BioPlex 2200 EBV IgM Control Set
BioPlex 2200 EBV IgM Calibrator Set

Indications for Use:

BioPlex 2200 EBV IgM Kit
The BioPlex 2200 EBV IgM kit is a multiplex flow immunoassay intended for the qualitative detection of two (2) separate analytes; Epstein-Barr Virus Viral Capsid Antigen (EBV VCA) IgM antibodies and Heterophile antibodies in human serum. The test system can be used in conjunction with the BioPlex 2200 EBV IgG kit as an aid in the laboratory diagnosis of infectious mononucleosis (IM).

The EBV IgM kit is intended for use with the Bio-Rad BioPlex 2200 System.

Assay performance characteristics have not been established for immunocompromised or immunosuppressed patients, cord blood, neonatal specimens, or infants. Assay performance characteristics have not been established for the diagnosis of nasopharyngeal carcinoma, Burkitt's lymphoma, and other EBV-associated lymphomas.

BioPlex 2200 EBV IgM Calibrator Set
The BioPlex 2200 EBV IgM Calibrator Set is intended for the calibration of the BioPlex 2200 EBV IgM Reagent Pack.

BioPlex 2200 EBV IgM Control Set
The BioPlex 2200 EBV IgM Control Set is intended for use as an assayed quality control to monitor the overall performance of the BioPlex 2200 Instrument and BioPlex 2200 EBV IgM Reagent Pack in the clinical laboratory. The performance of the BioPlex 2200 EBV IgM Control Set has not been established with any other EBV assays.

Prescription Use: ___X___ AND/OR Over-The-Counter Use: _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K062213